

# REISNER DECLARATION

## EXHIBIT A

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG CO.,  
INC., on behalf of itself and all others similarly  
situated,

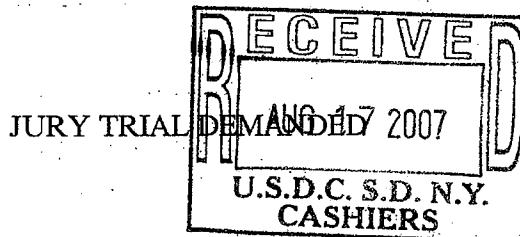
Plaintiff,

v.

SANOFI-AVENTIS, SANOFI-AVENTIS U.S.  
LLC, and AVENTIS PHARMACEUTICALS,  
INC.,

Defendant.

Civil Action No. \_\_\_\_\_  
ECF Case



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### CLASS ACTION COMPLAINT

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Plaintiff Louisiana Wholesale Drug Co., Inc. ("Plaintiff" or "Louisiana Wholesale"), on behalf of itself and all others similarly situated, for its Class Action Complaint ("Complaint") against defendants Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals, Inc. (collectively "Aventis" or "Defendant"), alleges as follows based on: (a) personal knowledge; (b) the investigation of Plaintiff's counsel; and (c) information and belief:

#### I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages arising out of Defendant's unlawful exclusion of AB-rated generic competition from the market for leflunomide, a pharmaceutical drug used for treatment of active rheumatoid arthritis (RA) to reduce signs and symptoms, and to retard structural damage as evidenced by X-ray erosions and joint space narrowing. Leflunomide is sold by Aventis under the brand name Arava, and sold by generic manufacturers under the chemical name leflunomide.

2. Aventis, and its predecessor entities, have been participants in the pharmaceutical industry for many years and have had, at all relevant times, a very sophisticated understanding of the economics and other inter-workings of this industry. For instance, Aventis is, and has been, fully aware of the realities of competition from AB-rated generic versions to branded drugs, and the inevitable significant decline in sales of a brand name drug once AB-rated generic versions of that drug come to market.

3. More specifically, AB-rated generic versions of brand name drugs contain the same active ingredient, and are found by the FDA to be just as safe and effective, as their brand name counterparts. This is due to the fact that AB-rated generic drugs are "bioequivalent" to their brand name drug counterparts, meaning they provide the same amount of active ingredient into a patient's bloodstream for the same amount of time as the branded drug.

4. The only material difference between generic drugs and their brand name counterparts is price. Generics are typically far less expensive than their brand counterparts, especially when there are multiple generic competitors on the market. As a result, AB-rated generics constitute both, (a) an opportunity for drug purchasers and consumers to obtain enormous cost savings, and (b) a serious threat to the monopoly power and profits of the manufacturer of the brand name drug facing generic competition. Indeed, AB-rated generic versions of brand name drugs typically take 80% or more of the sales of a brand name drug within a year of generic entry.

5. Knowing these realities of the pharmaceutical industry, Aventis was keenly aware that it would lose a substantial amount of its sales of Arava very quickly once AB-rated generics versions came to market. As described in more detail below, in order to delay this inevitable loss of sales revenue, Aventis engineered a scheme whereby it would, *inter alia*, delay

generic competition by filing an objectively baseless (*i.e.*, sham) Citizen Petition for the express purpose, and with the express intent, of delaying the FDA's final approval of the various leflunomide Abbreviated New Drug Applications ("ANDAs") which sought permission to market and sell AB-rated generic versions of Arava.

6. Aventis knew, based on the FDA's limited resources and practice of carefully considering all Citizen Petitions purporting to indicate threats to the public health before granting final approval to ANDAs – even frivolous ones such as at issue here – that the mere filing of a Citizen Petition would immediately delay FDA final approval of ANDAs seeking approval for AB-rated generic versions of Arava.

7. That is precisely what occurred in this case. On the eve of FDA approval of multiple ANDAs for leflunomide in March 2005, Aventis filed an objectively baseless, sham Citizen Petition with FDA regarding these ANDAs. As was, and is, FDA's practice, the FDA considered and ruled on the Citizen Petition prior to granting final approval to the ANDAs at issue. As expected, the FDA found that Aventis' Citizen Petition was completely without merit on September 13, 2005. See Exhibit 1. Immediately upon this ruling by FDA, the AB-rated generic versions of leflunomide were given final approval by FDA and came to market. But, Aventis obtained its desired result: FDA approval of the multiple leflunomide ANDAs, and hence market entry, was delayed by at least five (5) months.

8. Once AB-rated generic versions of leflunomide came to market, Aventis lost approximately 80% of its \$235 million annual sales of Arava in the U.S. to AB-rated generic leflunomide within three months.

9. Thus, as a result of its illegal scheme, and in violation of §2 of the Sherman Act, Aventis: (a) illegally maintained monopoly power in the market for leflunomide in the United

States for at least five (5) months; (b) fixed, raised, maintained, and/or stabilized the price of leflunomide at supra-competitive levels; and (c) overcharged Plaintiff and members of the Class (i.e., direct purchasers of Arava) by millions of dollars by depriving them of the results of competition from cheaper generic versions of Arava.

10. Aventis' extended period of monopoly power in the leflunomide market was maintained through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a legally-obtained market exclusivity, a superior product, business acumen or historic accident.

## II. JURISDICTION AND VENUE

11. This Complaint is filed, and these proceedings are instituted, under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover threefold damages in the form of overcharges, and the costs of suit and reasonable attorneys' fees, for the injuries sustained by Plaintiff and members of the Class of direct purchasers of Arava resulting from the violation by Aventis, as alleged herein, of Section 2 of the Sherman Act, 15 U.S.C. §2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. §15.

12. Aventis transacts business around the world, and within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

## III. THE PARTIES

13. Plaintiff Louisiana Wholesale Drug Co., Inc. ("Louisiana Wholesale") is a corporation organized under the laws of the State of Louisiana and is located at 20851-49, South

Service Road, in Sunset, Louisiana 70584. Louisiana Wholesale purchased Arava directly from Aventis during the Class Period, as defined below, and was injured in the form of overcharges by the illegal conduct described herein.

14. Defendant, Sanofi-Aventis, located at 174, avenue de France, 75013 Paris, France, is one of the world's largest pharmaceutical companies. Sanofi-Aventis sold, and/or authorized the sale of, Arava in the United States.

15. In the United States, Sanofi-Aventis conducts business and markets Arava through its affiliates, Defendant Sanofi-Aventis U.S. LLC, and/or Defendant Aventis Pharmaceuticals, Inc., incorporated under the laws of the State of Delaware, each with their principal place of business in the United States, in Bridgewater, New Jersey.

#### **IV. CLASS ACTION ALLEGATIONS**

16. Plaintiff brings this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

- a) All persons or entities in the United States who purchased 10 mg or 20 mg Arava tablets directly from Aventis (or any of its predecessors or affiliates) at any time from March 2005, until the anticompetitive effects of Defendant's conduct ceased (the "Class").
- b) Excluded from the Class are Defendant, and its predecessors, its officers, directors, management, employees, subsidiaries, parent or affiliates, and all federal governmental entities.

17. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes there are at least dozens of Class members spread across the United States. Moreover, the members of the Class are readily identifiable from information and records in the possession of Defendant.

18. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff

and all members of the Class were damaged in the same way by the same wrongful conduct of Aventis, *i.e.*, they paid artificially inflated prices for leflunomide and were deprived of the benefits of competition from cheaper generic versions of Arava as a result of Aventis' wrongful conduct.

19. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

20. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

21. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Aventis has acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendant's wrongful conduct.

22. Questions of law and fact common to the Class include:

- a. whether Defendant illegally maintained its monopoly power by improperly delaying generic entry through, *inter alia*, the filing of a sham Citizen Petition;
- b. whether direct proof of Defendant's monopoly power is available, and if available, whether it is sufficient to prove Defendant's monopoly power without the need to also define a relevant market;
- c. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
- d. whether the activities of Defendant as alleged herein have substantially affected interstate commerce; and
- e. whether, and to what extent, Defendant's conduct caused antitrust injury, and if so, the appropriate measure of damages.

23. Class action treatment is a superior method for the fair and efficient adjudication

of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

24. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

## V. FACTUAL ALLEGATIONS

### **A. The Regulatory Structure Pursuant to Which Generic Substitutes for Brand Name Drugs Are Approved**

25. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

26. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

27. The purpose of the Hatch-Waxman Act was twofold. First, Congress sought to expedite generic competition, and thereby reduce healthcare expenses nationwide, where a generic product could be developed that did not infringe any existing legitimate patent. Second,

Congress wanted to protect the incentive of pharmaceutical companies to create new and innovative products. The Hatch-Waxman Act achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies.

28. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

29. The ANDA relies on the scientific findings of safety and effectiveness included by the brand name drug manufacturer in the original NDA. The ANDA filer, however, must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand name drug. Bioequivalency is a demonstration that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the brand drug counterpart.

30. As a counter-balance to this abbreviated process for bioequivalent generic drugs, Hatch-Waxman streamlined the process for a brand name manufacturer to enforce legitimate patents it may have that cover its brand name drug against infringement by generic manufacturers. Hatch-Waxman also provided that, under certain conditions not present in this case, the FDA would refrain from granting a generic manufacturer final approval to market or sell its generic version of a brand name drug for up to 30 months if patent litigation over those drugs ensues.

31. Hatch-Waxman also provides brand name manufacturers with several means, in addition to traditional patent rights, to obtain legitimate protection from generic competition for

set, and specifically limited, periods of time. For example, each approved NDA provides the owner of that drug three (3) years of exclusivity during which time no generic can even file an ANDA. *See* 21 U.S.C. § 355(j)(5)(F)(iii). For pioneer drugs that are truly new or innovative in that they make use of a never-before-approved chemical entity or moiety – as opposed to an NDA relating to the far more common reformulations or dosage changes for existing drugs – the FDA grants an “New Chemical Entity” (“NCE”) exclusivity period of five (5) years. *See* 21 U.S.C. § 355(j)(5)(F)(ii). The FDA gives six (6) months of additional exclusivity to a branded drug that satisfactorily complies with an FDA request to conduct pediatric studies. *See* 21 U.S.C. § 355a(c)(2)(A); *see also, Barr Laboratories, Inc. v. Thompson*, 238 F.Supp.2d 236, 240 -241 (D.D.C. Dec 18, 2002). In addition, if an NDA drug treats a rare condition, FDA may grant an additional two (2) years of Orphan Drug exclusivity.

**B. Generic Versions of Brand Name Drugs are Significantly Less Expensive Than, and Take Significant Sales Directly From, the Corresponding Brand Name Versions**

32. Typically, AB-rated generic versions of brand name drugs are priced significantly below the brand name counterparts. Because of the price differentials, and other institutional features of the pharmaceutical market, AB-rated generic versions are rapidly and substantially substituted for their brand name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease significantly because of competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generics is dramatic.

33. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by both Congress (*i.e.*, the Hatch-Waxman Act) and most state legislatures (*i.e.*, Drug Product Selection, or “DPS laws”), pharmacists may (and, in most states,

must) substitute an AB-rated generic version of a drug for the brand name drug without seeking or obtaining permission from the prescribing doctor (unless the prescription is denominated "Dispense as Written," or "DAW"). Indeed, both Congress and the state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously (a) engaging in the type of heavy promotion or "detailing" typically done by brand name manufacturers, and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

34. Generic competition enables direct purchasers to (a) purchase generic versions of brand name drugs at substantially lower prices, and/or (b) purchase the brand name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug which competes with the brand name drug, and therefore, the brand name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand name sales. Consequently, brand name drug manufacturers have a strong interest to use various tactics, including the tactics alleged herein, to delay the introduction of AB-rated generic competition into the market.

### C. Citizen Petitions to the FDA

35. A person or entity, such as a pharmaceutical company, may file a Citizen Petition with the FDA requesting, among other things, that the FDA take, or refrain from taking, administrative action. See 21 CFR 10.30. Citizen Petitions may, for example, request that a pending ANDA not be approved. Citizen Petitions are intended to provide an opportunity for individuals to express their genuine concerns about safety, scientific, or legal issues regarding a product anytime before, or after, its market entry.

36. Federal regulations provide a 180 day period for the FDA Commissioner to

respond to each Citizen Petition. See 21 CFR 10.30(e)(2). The FDA may approve the Citizen Petition request, approve it in part, deny the request, or provide a tentative response with an estimate on a time for a full response.

37. Reviewing and responding to these petitions is often a resource-intensive and time consuming task because the FDA must, in addition to its already-existing workload, (a) research the Citizen Petition's subject matter, (b) examine scientific, medical, legal and sometimes economic issues, (c) consider public responses to the Citizen Petition, and (d) coordinate internal agency review and clearance of the petition response.

**D. Use of Citizen Petitions by Named Brand Drug Manufacturers As a Mechanism to Forestall Generic Competition**

38. In recent years, the Citizen Petition process has been subject to misuse by some brand name pharmaceutical manufacturers as a tactic to extend their monopolies on certain brand name brand drugs.<sup>1</sup> Often, Citizen Petitions by rival companies do not raise legitimate concerns about the safety or efficacy of generic products, but instead seek to preserve monopolies after the end of statutorily-granted patent or FDA exclusivity period(s). These Citizen Petitions are often filed on the eve of FDA approval of an ANDA for competing AB-rated generic drugs. Final approval of a pending ANDA is typically delayed for several months, but may be delayed for over a year, while the FDA evaluates the Citizen Petition.

39. Delayed generic competition is a lucrative outcome for an incumbent brand name manufacturer facing impending competition from an AB-rated generic(s). The cost of filing an improper, sham Citizen Petition is trivial compared to the value of securing several additional months of monopoly profits.

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<sup>1</sup> See Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, at <http://www.ftc.gov/be/v000005.pdf>, at p. 1, *et seq.*

40. FDA officials have acknowledged ongoing abuses of the Citizen Petition process.

FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency, he had "seen several examples of Citizen Petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."<sup>2</sup>

41. In July 2006, Gary Buehler, Rhp., Director of the Office of Generic Drugs Center for Drug Evaluation and Research ("CDER") at the FDA, noted that of 42 Citizen Petitions raising issues about the approvability of generic products, "very few ... have presented data or analysis that significantly altered FDA's policies." Of these 42, only three (3) petitions led to a change in the Agency's policy on the basis of data or information submitted in the Citizen Petition.

42. As a general matter, the FDA has limited resources to devote to all aspects of drug regulation, including consideration and resolution of all Citizen Petitions that are filed. In addition, as a practical matter, the FDA must first review the issues raised in a Citizen Petition before it can be in a position to grant or deny a petition, even a frivolous one. As a result, while there is no statutory requirement that the FDA withhold approval of an ANDA while a Citizen Petition is pending, it is the practice of the FDA, well known in the pharmaceutical industry, to consider and respond to a Citizen Petition prior to approval of an ANDA. On this subject Mr.

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<sup>2</sup> These comments were made by FDA Chief Counsel Sheldon Bradshaw in a speech before the Generic Pharmaceutical Association Annual Policy Conference on September 19, 2005, just days after the FDA had denied Aventis' Citizen Petition at issue here. <http://www.gphaonline.org/AM/Template.cfm?Section=Home&CONTENTID=2234&TEMPLATE=/CM/ContentDisplay.cfm>; at p. 21, et seq.

Buehler acknowledged, “[i]t is very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the Citizen Petitions.”

43. Given this regulatory scheme and practice, and the nature of the pharmaceutical industry (particularly the economics), the potential and incentive for abuse of the Citizen Petition process by brand name manufacturers is great.

**E. Aventis' Unlawful Scheme to Delay AB-Rated Generic Competition for Arava**

44. Aventis' Arava (leflunomide) was approved for sale in the United States by the FDA on September 10, 1998, in strengths of 10 mg, 20 mg and 100 mg. The usual daily dose of Arava is 20 mg. The 10 mg dosage is used in patients who do not tolerate the 20 mg dose adequately.

45. The use of a “loading dose” of 100 mg per day for three (3) days is recommended in Arava's approved labeling. The use of the loading dose is not essential to the effective use of the product, and elimination of the loading dose may actually decrease the risk of adverse events for some patients.

46. As filer of the NDA for Arava, Aventis enjoyed the exclusive FDA regulatory right to market Arava in all three dosage forms for five (5) years pursuant to section 505(j)(5)(F)(ii) of the FDCA, even though Arava did not have patent protection from the generic competitors at issue here. In addition, because the FDA determined that, under section 505(A) of the FDCA, Arava was entitled to pediatric exclusivity, the period of exclusive marketing of Arava by Defendant was extended six (6) months. Defendant's exclusive right to market Arava ended on March 10, 2004. During these periods no generic manufacturer was entitled to even file an ANDA with the FDA seeking approval for an AB-rated generic version of Arava.

47. With knowledge of the timing of the various exclusivity periods applicable to Arava, and the lack of patent protection, Aventis was fully aware of when generic manufacturers would be filing ANDAs and the approximate periods in which FDA would approve such ANDAs. Based on this knowledge, Aventis devised a strategy to delay entry of generic manufacturers into the market for 10 mg and 20 mg leflunomide tablets.

48. In September 2002, four years after obtaining FDA approval for Arava, and over a year before its exclusivity was set to expire, Defendant stopped selling the 100 mg loading dose of Arava. Instead, Defendant began supplying the loading dose as a free sample to physicians in the form of a blister pack containing three 100 mg tablets of Arava.

49. Defendant stopped selling the 100 mg tablets in anticipation of the loss of market exclusivity as a means of providing a pretext for interfering with generic entry into the more lucrative 10 mg and 20 mg markets. Providing the loading dose for free disincentivized any generic manufacturer from sponsoring an ANDA with respect to the 100 mg tablet, as the product was available free to physicians from Aventis. Defendant later attempted to use the fact that no ANDA filers were seeking approval for the 100 mg tablet to argue that any ANDA for the 10 mg and 20 mg dosages could not be approved unless and until (a) the ANDA also sought approval for the 100 mg dosage, or (b) the ANDA filer satisfied additional bioequivalence testing which was specifically not required by federal regulations.

50. As mentioned above, pursuant to 505(c)(3)(E)(ii) of the FDCA, no ANDA could be submitted until the expiration of Defendant's regulatory exclusivity period for Arava on March 10, 2004.

51. Not surprisingly, on or about March 10, 2004, several generic manufacturers, including Kali Laboratories, Barr Laboratories, TEVA Pharmaceuticals, Apotex Corp., and

Sandoz, Inc., filed ANDAs with the FDA, each seeking approval to market AB-rated generic versions of 10 mg and 20 mg tablets of Arava (leflunomide).

52. On March 31, 2005, more than a year after the various leflunomide ANDAs were filed, Aventis filed a Citizen Petition with the FDA, pursuant to 505(j) of the FDCA, in order to delay all AB-rated generic versions of Arava from entering the United States market. A copy of that Citizen Petition is attached hereto as Exhibit 2.

53. Aventis' Citizen Petition urged the FDA to withhold approval of any ANDA that did not also seek approval of a 100 mg leflunomide tablet that is bioequivalent to Defendant's Arava 100 mg tablets or did not establish *in vivo* bioequivalence between five 20 mg leflunomide tablets and one Arava 100 mg tablet.

54. Aventis' Citizen Petition, which was filed on the eve of the FDA's approval of the various ANDAs for generic leflunomide, used arguments and citations that were known and available to Aventis well before it submitted the Citizen Petition to the FDA. The FDA's response to Aventis' Citizen Petition, issued on September 13, 2005, made special note of these facts. A copy of the FDA's response to Defendant's Citizen Petition is attached hereto as Exhibit 1.

55. Specifically, in its Citizen Petition, Aventis argued that in order to market a 10 mg or a 20 mg generic version of Arava, an ANDA applicant must provide evidence of bioequivalence of five of its 20 mg generic tablets to the 100 mg branded Arava tablet – even if the ANDA does not seek approval to sell a 100 mg generic tablet – or submit an ANDA for a 100 mg strength generic tablet. Aventis premised this argument on the fact that, while evaluating Aventis' NDA – which did seek approval for a 100 mg tablet – the FDA had required Aventis to provide evidence of bioequivalence between five 20 mg tablets of branded Arava and

the 100 mg strength before Aventis could obtain approval for the use of five 20 mg tablets as the 100 mg "loading dose".

56. Aventis also argued that any label for generic leflunomide 10 mg or 20 mg tablets for which the generic manufacturer did not also seek and obtain approval for a 100 mg loading dose would need to omit any mention of a loading dose and would therefore render the generic formulations "less effective" than Arava, and therefore not capable of final FDA approval under applicable FDA labeling regulations.

57. Specifically, Aventis' petition stated that, "Aventis believes that these [generic] applicants are instead seeking to include a loading dose of five 20 mg leflunomide tablets or seeking to exclude the loading dose [from the labeling] altogether." This was a false statement, and Aventis had no basis for making it. The ANDAs of the various generic manufacturers contained no proposal to use five 20 mg leflunomide tablets as a loading dose or to omit mention of a loading dose in their labeling. See Exhibit 1.

58. Aventis knew its Citizen Petition was objectively baseless and a sham because, as a sophisticated pharmaceutical company with extensive experience with the FDA approval process, it was aware that (among other things) generic Arava labeling could indicate a 100 mg loading dose (a) regardless of whether or not the generic manufacturer marketed a 100 mg dose, and (b) without demonstrating bioequivalence of five 20 mg tablets to one 100 mg Arava tablet. It is clear Aventis' Citizen Petition was not submitted to influence FDA policy or address any legitimate concern about the efficacy or safety of generic leflunomide, but was submitted solely to forestall generic competition in the United States market for leflunomide during the time it would take the FDA to evaluate and respond to the Citizen Petition.

59. Defendant's Citizen Petition ignored the fact that the FDCA and bioequivalence

regulations do not require that an ANDA sponsor demonstrate equivalence between different strengths of its own product line, only that it demonstrate bioequivalence between the dosage of the drug which is the subject of the ANDA and the name brand drug of the same dosage. See 21 C.F.R. Part 320. Further, there are no regulations which require an ANDA applicant to seek approval for all strengths of the reference listed brand name drug (here, Arava).

60. As the FDA response points out, the fact that generic manufacturers only sought to market the 10 mg and 20 mg did not necessitate that they omit any mention of a loading dose for leflunomide in their labeling. The FDA stated that, “[Aventis] seem[s] to ignore a third possibility: that the labeling for a generic leflunomide product can recommend a loading dose of 3 x 100 mg that can be accomplished by the use of an approved 100 mg tablet from a different manufacturer. Given the unusual manner in which the 100 mg tablet for the loading dose has been distributed by Aventis (i.e., in blister packs of 3, for free and only to, and at the request of, a physician) and the fact that there are circumstances when a loading dose should perhaps not be used, we do not find it unreasonable for a generic manufacturer to elect to market only the other dosage strengths.” *See, Exhibit 2, at p. 6.*<sup>3</sup>

61. The FDA also found that the “[Aventis] Comment acknowledges that an ANDA applicant that seeks approval of a 20-mg leflunomide tablet, but not a 100-mg tablet, could propose to ‘reference [in the drug’s label] a 100 mg tablet that the generic does not manufacture’

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<sup>3</sup> *See also, Exhibit 1, at pp. 6 – 7,8 (“Labeling for generic leflunomide products approved in 10- and 20-mg strengths may reference a 100-mg leflunomide tablet that the generic sponsor does not produce. As reflected by existing precedents, ANDA sponsors may refer in their labeling to products they do not manufacture.... It is also not uncommon for brand name products to refer in their labeling to other drugs that are not provided by the sponsor of the brand name product (e.g., the labeling of Oncaspar – an Aventis product, recommends its use in combination with the following products not made by Aventis: vincristine; methotrexate, cytarabine, daunorubicin, and doxorubicin; also, the labeling of Eloxatin, owned by Sanofi-Synthelabo, Inc., recommends that it be used in combination with infusional 5-FU/LV[5-fluorouracil/leucovorin], which Sanofi-Synthelabo, Inc., does not supply.).”*

(Comment at 3). You go on to assert that this option should not be permitted (Id.); however, you provide no explanation for your assertion, and, for the reasons discussed in the text above, we see no reasoned basis to accept it.”<sup>4</sup> Exhibit 1 at p. 6, fn 14.

62. On September 13, 2005, the FDA denied Aventis’ Citizen Petition and also granted final approval to the ANDAs sponsored by Kali Laboratories, Barr Laboratories, TEVA Pharmaceuticals, Apotex Corp., and Sandoz, Inc., for the 10 mg and 20 mg dosage tablets of leflunomide. These generic manufacturers, as well as Prasco Laboratories, under an agreement with Defendant to sell an “authorized generic” version leflunomide, began selling generic Arava in the United States market on September 14, 2005.

63. As a direct and proximate result of Aventis’ unlawful conduct, Plaintiff Louisiana Wholesale and the Class were denied the benefits of free and unrestrained competition in the market for leflunomide from March 31, 2005, the date of Aventis’ Citizen Petition, until September 14, 2005, the date when generic leflunomide became available in the United States. The effects of Aventis’ anticompetitive scheme may actually extended beyond September 14, 2005, as a result the economic realities of the pharmaceutical industry which cause the full extent and benefit of generic penetration to not occur immediately upon market entry.

64. More specifically, Louisiana Wholesale and members of the Class were denied the opportunity to purchase lower-priced AB-rated generic versions of Arava, and were thereby forced to pay supra-competitive prices for leflunomide.

65. Aventis’ actions are part of, and in furtherance of, the illegal monopolization scheme alleged herein, and were authorized, ordered or done by Aventis’ officers, agents,

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<sup>4</sup> The FDA’s response to a Citizen Petition is considered an official position of the FDA. See 21 C.F.R. §10.45(d). (“Unless otherwise provided, the Commissioner’s final decision constitutes final agency action (reviewable in the courts under ...)”)

employees or representatives while actively engaged in the management of Aventis' affairs.

66. Aventis' illegal acts to delay the introduction and/or dissemination into the U.S. marketplace of any generic version of Arava resulted in Plaintiff and the Class paying more than they would have paid for leflunomide, absent Aventis' illegal conduct.

#### G. Effect on Interstate Commerce

67. At all material times, Arava, manufactured and sold by Aventis, was shipped across state lines and sold to customers located outside its state of manufacture.

68. During the relevant time period, in connection with the purchase and sale of Arava, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

69. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Aventis, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

70. Aventis' exclusionary conduct impeded the sale of generic leflunomide in the United States, and unlawfully enabled Aventis to sell Arava at monopolistic, artificially inflated prices. By engaging in such conduct, Aventis harmed the competitive process, and illegally maintained its ability to extract supra-competitive prices from purchasers of leflunomide. But for Aventis' illegal conduct, generic competitors would have been able to compete for sales of 10 mg and 20 mg Arava in March 2005, and Plaintiffs, members of the Class, and other purchasers would have benefited from that competition by paying lower prices for leflunomide.

71. There are no procompetitive justifications for Aventis' conduct. The conduct alleged above created no efficiency gains or increases in consumer welfare. On the contrary,

Aventis' conduct substantially decreased or eliminated the efficiency gains that would otherwise have occurred through the earlier introduction of less expensive AB-rated generic versions of Arava that could be substituted at the pharmacy counter for branded Arava – efficiency gains that Congress and state legislatures intended to bring about when they enacted Hatch-Waxman and state generic substitution laws.

72. As a result of Aventis' unlawful and exclusionary conduct, Louisiana Wholesale and members of the Class continued to purchase branded Arava from Aventis at monopoly prices rather than generic leflunomide from generic manufacturers at lower prices and Arava from Aventis at lower prices.

#### G. Monopoly Power and Relevant Market

73. Direct proof exists that Aventis had monopoly power over the price of leflunomide. Such direct evidence includes transactional data showing a significant, non-transitory decline in leflunomide prices immediately upon entry of generic leflunomide that had not occurred until generic entry. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether Aventis had monopoly power.

74. Assuming, *arguendo*, that a relevant market needs to be defined, the relevant product market is leflunomide, *i.e.*, Arava and any AB-rated generic equivalents. The relevant geographic market is the United States and its territories. A firm that was the only seller of such products in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by Aventis' ability to profitably charge supra-competitive prices during the period in which it lacked generic competition. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which leflunomide is prescribed.

75. Through the anticompetitive conduct alleged herein, Aventis was able to profitably charge supra-competitive prices for leflunomide without losing substantial sales, and thus, by definition, maintained monopoly power with respect to leflunomide sold in the United States.

76. Prior to generic entry in September 2005, Aventis' market share in the relevant market was 100%. After market entry by generic manufacturers with much cheaper generic version of Arava, Aventis' market share for this drug product declined dramatically in a short period of time

#### H. Effects on Competition and Damages to Plaintiff and Class

77. Aventis' actions were intended to suppress, rather than promote, competition on the merits, and have had precisely the intended effect.

78. Louisiana Wholesale and members of the Class have been injured in their business and property by reason of Aventis' unlawful monopolization. Plaintiff's injury consists of paying higher prices for leflunomide than would have been paid in the absence of Aventis' illegal conduct. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Aventis' conduct unlawful.

79. Defendant's exclusionary conduct delayed the sale of generic leflunomide in the United States, and unlawfully enabled Aventis to sell Arava at artificially inflated prices. But for Defendant's illegal conduct, multiple generic competitors would have been able to successfully market AB-rated generic versions of Arava capsules by March 2005 – approximately five months before they were actually able to obtain FDA approval and come to market.

80. If manufacturers of generic Arava had entered the marketplace and effectively competed with Aventis earlier, as set forth above, Louisiana Wholesale and other members of the

Class would have substituted lower-priced generic leflunomide for the higher-priced brand name Arava for some or all of their leflunomide requirements, and/or would have received a lower price (and/or discounts) on some or all of their remaining Arava purchases.

**COUNT I – Monopolization in Violation of Section 2 of the Sherman Act**

81. Plaintiff repeats, and incorporates by reference, the allegations above in ¶¶ 1 – 80 above.

82. Aventis used willful and exclusionary means as part of a scheme described herein to improperly maintain and extend their monopoly power in the leflunomide market, as detailed above.

83. The goal, purpose and effect of Aventis' scheme was to prevent, delay, and/or minimize the success of the entry of AB-rated generic leflunomide competitors which would have sold generic leflunomide in the United States at prices significantly below Defendant's prices for Arava, which would have effectively caused the average market price of leflunomide to decline dramatically.

84. The goal, purpose and effect of Aventis' scheme was also to maintain and extend its monopoly power with respect to leflunomide. Aventis' illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of Arava enabled Aventis to continue charging supra-competitive prices for leflunomide without a substantial loss of sales.

85. As a result of Aventis' illegal conduct, Plaintiff and the Class paid more than they would have paid for leflunomide, absent Aventis' illegal conduct. But for Aventis' illegal conduct, competitors would have begun marketing generic versions of Arava well before they actually did.

86. If manufacturers of generic leflunomide entered the market and competed with Aventis in a full and timely fashion, Plaintiff and other Class members would have substituted lower-priced generic leflunomide for the higher-priced brand name Arava for some or all of their leflunomide requirements, and/or would have received lower prices on some or all of their remaining Arava purchases.

87. Aventis' scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for leflunomide in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

## **VI. JURY TRIAL DEMANDED**

88. Plaintiff demands trial by jury on all issues so triable.

## **VII. PRAYER FOR RELIEF**

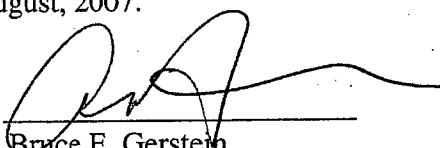
**WHEREFORE**, Plaintiff, on behalf of itself and the Class, respectfully prays that:

- (i) The Court determine that this action may be maintained as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;
- (ii) The acts alleged herein be adjudged and decreed to be unlawful and willful acts of monopolization in restraint of trade in violation of Section 2 of the Sherman Act;
- (iii) The Class be awarded three-fold the damages determined to have been sustained by the Class, and that judgment be entered against Aventis in favor of the Class;

(iv) The Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and

(v) The Class be granted such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Respectfully submitted, this 14<sup>th</sup> day of August, 2007.

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